Key Facts about

Emergency Contraception

for

Emergency Department Staff Who Provide Care to Sexual Assault and Rape Survivors[1]

This fact sheet has been prepared by the Massachusetts Department of Public Health pursuant to Chapter 91 of the Acts of 2005 and reflects current medical research and standards of practice. Physicians and staff who provide care to sexual assault and rape survivors remain responsible for providing care in accordance with their professional training, expertise and judgment.

Emergency Contraception (EC) is considered to be a safe and effective way to prevent pregnancy after sexual assault or rape.[2]

Taking EC after a sexual assault or rape decreases a woman's chances of becoming pregnant.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills (EC pills) contain the same medication as regular birth control pills. There are two basic types of pills that are used as Emergency Contraception.

- **Progestin-only pills:** Plan B™[3] is a dedicated product that is FDA approved it for use as EC.
  Dosing: Provide first dose as soon as possible after the sexual assault or rape, second dose 12 hours later.[3]
  Recent research shows equal efficacy if both doses are taken simultaneously.[4]

- **Combined Estrogen/Progestin pills:** High doses of Oral Contraceptive Pills (OCPs)[3] have been determined by the FDA to be safe and effective for use as Emergency Contraception.[5]
  Dosing: Type of OCP and number varies.[6]

How do EC pills work?

Physiological effects of EC pills result in 3 possible mechanisms of action in preventing pregnancy. They may work by:[7]

- Delaying or inhibiting ovulation;
- Inhibiting fertilization; or
- Preventing implantation of the fertilized egg.

EC pills should be started as soon as possible after the sexual assault.

- The sooner a woman takes EC pills after a sexual assault or rape, the more effective it is.
- EC pills are most effective when taken in the first 12 hours.[8]
- The FDA has approved EC pills to be initiated up to 72 hours (3 days).
- Recent research has shown EC pills initiated up to 120 hours[9] are effective.

EC pills are considered to be safe and effective.

- Progestin-only pills reduce pregnancy risk by 89%*[10] if taken within 72 hours of a sexual assault or rape.
- Combined estrogen/progestin pills reduce pregnancy risk by 75%*[10] if taken within 72 hours of a sexual assault or rape.
- Using EC pills will not affect a woman's ability to become pregnant in the future.[11]
- If EC pills are taken when the woman is pregnant or if pregnancy occurs despite use, they will not harm the developing fetus.[12]

Contraindications and side effects.

- Contraindications:[3]
  - Known, established pregnancy reported by the patient.
  - Known hypersensitivity to any component of the product.
- Side Effects:[3]
  - Some women may experience nausea and vomiting. These symptoms are more common with the combined estrogen/progestin pills than with progestin only pills.
  - Other side effects may include short term fatigue, headache, dizziness, breast tenderness, or a change in the timing of the next period.

Medical follow up after taking EC pills for sexual assault or rape survivors.

- If patient vomits within 2 hours of taking EC pills, patient should be advised to immediately contact the medical provider for further instructions as a repeat dose may be advised.[13]
- If menses does not occur within 3 weeks of EC pills use, a pregnancy test is indicated.
- Regular contraception can be started immediately after EC pills, or with the next menses.
- EC pills do not prevent sexually transmitted infections or HIV.

For Additional Information Refer to the Product's Package Insert

*Pregnancy risk reduction based on one time use.

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1 This fact sheet is pursuant to sections of chapter 91 of the Acts of 2005, *An Act Providing Timely Access to Emergency Contraception*, which will take effect on December 14, 2005.

2 World Health Organization. "Emergency Contraception: A Guide to the Provision of Services." Geneva; WHO, 1998. Hatcher Richard A, et al., Contraceptive Technology, New York; Ardent Media Inc., 1998. Dailard, C. "Increased Awareness Needed to Reach Full Potential of Emergency Contraception." The Guttmacher Report on Public Policy, 2001; 4(3). Task Force on Postovulatory Methods of Fertility Regulation, "Randomized Controlled Trial of Levonorgestral Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency," Lancet, 1998; 352: 428-433. Glasier, A, Baird, D S. "The effects of self-administering Emergency Contraception." New England Journal of Medicine, 1998; 339(1): 1-4. Grimes, R, E, & Scott Jones, B. "Emergency Contraception Over-The-Counter: The Medical and Legal Imperatives." Obstetrics & Gynecology, 2001; 98(1): 151-155. The Alan Guttmacher Institute. "Emergency Contraception Improving Access." Issues In Brief, 2003; 3. The Henry J Kaiser Family Foundation, "Fact Sheets: Emergency Contraception," Menlo Park, CA; Kaiser Family Foundation, November 2000.

3 Refer to the product's package insert for details.

4 Recent WHO data (Lancet 2002; 360:1803-1810) for levonorgestrel showed that a 1.5mg *single dose* can substitute two 0.75mg doses 12h apart. This simplifies the use of levonorgestrel without an increase in side effects. Pregnancy rates were slightly lower for the single dose regimen, but not statistically significant. Similar findings on single dose efficacy were obtained by Arowojulu et al (Contraception 2002; 66:269-273).

5 The Commissioner of the Food and Drug Administration has concluded that combined oral contraceptives, taken initially within 72 hours of unprotected intercourse and providing a total of 0.10 or 0.12 mg of ethinyl estradiol and 0.50 or 0.60 mg of levonorgestrel in each of two doses separated by 12 hours, are safe and effective for use as post-coital emergency contraception (Federal Register 2/25/1997; Vol. 62, No. 37: 8610-8612).

6 Hatcher, Robert A, et al, Managing Contraception 2003-2004. Tiger, GA: Bridging the Gap Foundation, 2003. World Health Organization. "Selected Practice Recommendations for Contraceptive Use, Second Edition 2004." 2004. Geneva: WHO.

7 Swahn ML, Westlund P, Johannisson E, Bygdeman M. Effect of post-coital contraceptive methods on the endometrium and the menstrual cycle. Acta Obstet Gynecol Scand 1996;75:738-744. Ling WY, Robichaud A, Zayid I, Wrixon W, MacLeod SC. Mode of action of dl-norgestrel and ethinylestradiol combination in postcoital contraception. Fertil Steril 1979;32:297-302. Rowlands S, Kubba AA, Guillebaud J, Bounds W. A possible mechanism of action of danazol and an ethinylestradiol/norgestrel combination used as postcoital contraceptive agents. Contraception 1986;33:539-545. Croxatto HB, Fuentalba B, Brache V, Salvatierra AM, Alvarez F, Massai R, Cochon L, Faundes A. Effects of the Yuzpe regimen, given during the follicular phase, on ovarian function. Contraception 2002;65:121-128. Glasier A. Emergency postcoital contraception. N Engl J Med 1997;337:1058-1064. Ling WY, Wrixon W, Acorn T, Wilson E, Collins J. Mode of action of dl-norgestrel and ethinylestradiol combination in postcoital contraception. III. Effect of preovulatory administration following the luteinizing hormone surge on ovarian steroidogenesis. Fertil Steril 1983;40:631-636. Croxatto HB, Devoto L, Durand M, Ezcurra E, Larrea F, Nagle C, Ortiz ME, Vantman D, Vega M, von Hertzen H. Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature. Contraception 2001;63:111-121. Croxatto HB, Ortiz ME, Müller AL. Mechanisms of action of emergency contraception. Steroids 2003;68:1095-1098. Taskin O, Brown RW, Young DC, Poindexter AN, Wiehle RD. High doses of oral contraceptives do not alter endometrial a1 and a.ß3integrins in the late implantation window. Fertil Steril 1994;61:850-855. Raymond EG, Lovely LP, Chen-Mok M, Seppälä M, Kurman RJ, Lessey BA. Effect of the Yuzpe regimen of emergency contraception on markers of endometrial receptivity. Hum Reprod 2000;15:2351-5. Kubba AA, White JO, Guillebaud J, Elder MG. The biochemistry of human endometrium after two regimens of postcoital contraception: a dl-norgestrel/ethinylestradiol combination or danazol. Fertil Steril 1986:45:512-516. Ling WY, Wrixon W, Zayid I, Acorn T, Popat R, Wilson E. Mode of action of dl-norgestrel and ethinylestradiol combination in postcoital contraception. II. Effect of postovulatory administration on ovarian function and endometrium. Fertil Steril 1983;39:292-297. Yuzpe AA, Thurlow HJ, Ramzy I, Leyshon JI. Post coital contraception—a pilot study. J Reprod Med 1974; 13:53-58.

8 Piaggo, G. von Hertzen H, Grimes DA, Van Look PFA. "Timing of emergency contraception with levonorgestrel or the Yuzpe regimen." Lancet. 1999;353;721.

9 Recent WHO data (Lancet 2002; 360:1803-1810) for levonorgestrel collected from a large (n=2758) randomized trial conducted in 10 developed and developing countries showed that it prevented a high proportion of pregnancies if taken with within *five* days of unprotected intercourse. Rodrigues et al (Am J Obstet Gynecol 2001;184:531-537) reported similar findings for the Yuzpe regimen. Both studies, however, suggest lower efficacy with longer delay between treatment and unprotected intercourse. World Health Organization. "Selected Practice Recommendations for Contraceptive Use, Second Edition 2004." 2004. Geneva: WHO.

10 Hatcher Richard A, et al., Contraceptive Technology, New York; Ardent Media Inc., 1998.Alan Guttmacher Institute, "Emergency Contraception: Improving Access," Issues In Brief, 2003; 3.American College of Obstetricians and Gynecologists. "Emergency Contraception." ACOG Practice Bulletin Number 25, Washington DC; ACOG, 2001.Dailard, C. "Increased Awareness Needed to Reach Full Potential of Emergency Contraception." The Guttmacher Report on Public Policy, 2001; 4(3). Task Force on Postovulatory Methods of Fertility Regulation, "Randomized Controlled Trial of Levonorgestral Versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency," Lancet, 1998; 352: 428-433. The Contraception Report. "Levonorgestrel Alone for Emergency Contraception." 1999; 9(6):13-14. Boonstra, H. "Emergency Contraception: The Need to Increase Public Awareness." The Guttmacher Report on Public Policy, 2002; 5(4). World Health Organization. "Emergency Contraception: A Guide to the Provision of Services." 1998. Geneva: WHO. www.who.int/reproductive-health/publications/FPP_98_19/FPP_98_19_abstract.en.html

11 Plan B package insert

12 Raman-Wilms L. et al "Fetal genital effects of first-trimester sex hormone exposure: a meta-analysis. Obstet Gynecol. 1995; (85(1):141-9. McCann, M. F. and Potter, L.S. "Progestin-only oral contraception: A comprehensive review." Contraception. 1994;50(6) (S1):S9-195. Bracken M. B. "Oral contraception and congenital malformations on offspring: A review and meta-analysis of the prospective studies. Obstet Gynecol 1990;76:552-57 . "OPRR Reports: Protection of Human Subjects. Code of Federal Regulations 45CFR 46, March 8, 1983. 25 Hughes EC (ed), Committee on Terminology, The American College of Obstetricians and Gynecologists, Obstetric-Gynecologic Terminology. Philadelphia PA: F.A. Müller AL, Llados CM, Croxatto HB. Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. Contraception 2003;67:415-419. Davis, Daniel "Teratogenic Risk of Hormonal Products for Contraception: A Review of Literature." Division of Reproductive/ Urologic Drug Products, 5600 Fishers Lane, Rockville, MD.

13 World Health Organization. "Emergency Contraception: A guide to the provision of services." Geneva: WHO, 1998.